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10/783,522

02/20/2004

Roy Lurie

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EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/783,522	Applicant(s) LURIE ET AL.	
	Examiner PABLO WHALEY	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/29/2011, 3/21/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments and remarks, filed 02/18/2011, are acknowledged.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-50 are currently pending and under consideration.

Claim 51 is cancelled.

Information Disclosure Statement

The IDS filed 03/29/2011 has been considered in full.

The IDS filed 03/21/2011 has been considered in full.

Claim Rejections - 35 USC § 101

Response to Arguments

Applicant's arguments regarding the rejection of claims 1-11, 28-36, 45-50 under 35 U.S.C. 101 have been fully considered. This rejection is withdrawn in view of applicant's amendments.

Claim rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity

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and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claims 1, 12, 22, 28, 37, and 45 are also rejected due to said dependency.

Claims 1, 12, 22, 28, 37, and 45, on lines 7-11, are directed to method, device, and computer readable medium comprising instructions that cause a computer to "store a simulation context..., the storing making the simulation context available after the simulation finishes so that the simulation may be restored to a state consistent with the simulation context." The phrase "so that the simulation may be restored..." renders the claim indefinite because it is unclear in what limitation of the storing step is intended. For example, is this phrase intended to be an active method step (e.g. restoring the simulation...) or an intended use? If the former, it is then unclear in what way a simulation is restored to "a state consistent with the simulation context". The term "consistent with" is subjective and no standard is provided in the claim or specification. If the latter, is this phrase intended to be an intended use of the simulation context? Clarification is requested. This rejection could be overcome, for example, by amending

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the claims to recite positive limitations such as making the simulation context available to the simulation engine after the simulation finishes.

Response to Arguments

Applicant's arguments, filed 02/18/2011, have been fully considered but are not persuasive for the following reasons.

In response to applicant's argument(s) on page(s) 13, which states the above phrase "makes the context available in a manner that allows the simulation to be restored to a state consistent with the simulation context," the claims do not recite a step for "restoring" said simulation. Therefore applicant is arguing limitations not in the claims, and applicant's have not provided any arguments or amendments that clarify what function is intended by the phrase "so that the simulation may be restored to a state consistent with the simulation context." For these reasons, the rejection is MAINTAINED.

Claim Rejections - 35 USC § 112, 1st Paragraph

Response to Arguments

Applicant's arguments regarding the rejection of claims 1-50 under 35 U.S.C. 112, first paragraph, have been fully considered. This rejection is withdrawn in view of applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

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subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejections have been modified in view of applicant's amendment.

Claims 1-3, 5-14, 16-23, 25-30, 32-36 are rejected under 35 U.S.C. 103(a) as being made obvious by Lett et al. (WO 02/099736; Published 12 December, 2002; IDS filed 11/08/2004), in view of Cook (The Design of a Simulation System for Persistent Object Storage Management; University of Colorado; March 1993; p.1-23).

CLAIM SUMMARY

The claims, as best understood, are drawn to a method, program, and system for performing the following steps: generating results from executing a block diagram model of a biological process by performing a simulation of the block diagram model with a simulation engine; storing a simulation context of the simulation by registering an area of memory that constitutes the simulation context, wherein the simulation context comprises one or more values for one or more attributes, and the values are established during the simulation of the block diagram model; making the simulation context available after the simulation finishes for the purpose of restoring the entire simulation context; gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted; comparing the generated result to the data gathered from the experimental device using an analysis environment that is in communication with the simulation engine; and modifying the model of the biological process based on the comparison to correct the model of the biological process.

PRIOR ART

Lett teaches a computational method and system for updating or modifying biological simulation models [Abstract and p.10-12]. In particular, Lett teaches numerous simulation models for making predictions about biological or physiological systems based on time-series analysis, and describes the process using a block diagram [See at least p.22 and Fig. 2], which reads on generating results according to a block diagram model. These simulation models are each interpreted as “simulation

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contexts”, since the instant specification neither defines nor sufficiently describes this term to distinguish it from the models of the prior art.

Model parameters and information related to the state of the system are stored in memory [see page 12, last ¶, and Figure 1], including both RAM and secondary memory. Additionally, the computer can be accessed over the internet or physically integrated with another system [page 13, ¶1].

Lee shows obtaining data from a gene-chip and microarray data [Ref. claims 18, 19, and p.18] and from experimental imagers [p.11-12], which shows gathering data from an in-situ experimental device since the data is obtained over time.

The simulation model generates predicted images that are compared with acquired images [p.14]. The simulation model is then modified to improve the goodness of fit between predicted and obtained images [See at least p.14, last ¶, and p.24], which shows a modifying a model based on a comparison to correct the model. In particular, numerical intensity values are used to compare images [p.15], which is a teaching for values established during a simulation context.

The simulation model includes program code for performing the simulations [p.37]. Lett teaches calculating error measures that correlate with the difference between the predicted and acquired images [p.17]. Lett teaches a display for displaying simulation results to a user [See at least Fig. 1 and 2]. Regarding limitations directed to the simulation context comprising values that are established during the simulation of the block diagram model, Lett shows feedback loops and calculating variables throughout the simulation process [See e.g. p.11-12, 22, and 36].

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Lett does not teach a simulation engine that stores a simulation context by registering an area of memory that constitutes the simulation context, as in claims 1, 12, 22, and 28.

Lett does not teach a simulation engine that makes the simulation context available after the simulation finishes, as in claims 1, 12, 22, and 28.

Lett does not teach a simulation engine that restores the simulation context, as in claims 1, 12, 22, and 28.

Cook teaches a method for designing simulations systems and storing data. In particular, Cook teaches modules for both reading and writing data to physical memory locations as well as for registering memory to physical locations [Section 3.1, p.6-7, and Table 1]. Cook also describes a persistent data interaction process that includes reading memory, performing simulation, and passing the data with changes back to the persistent data system for the benefit of obtaining persistence (i.e. consistency) and improving overall efficiency [Section 3.3, p.10].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have stored the simulation programs of Lett by registering them within specific areas of memory, with a reasonable expectation of success, since Lett shows storing simulation programs and related parameters to memory, as set forth above, and since one skilled in the art would have recognized that writing programs and related data to memory, such as physical hardware memory, requires registering it to specific locations (i.e. area) within the physical memory, as shown by Cook. The

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motivation would have been to combine prior art elements according to known methods to yield predictable results

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have modified the computational method and system of Lett by making the simulation context available after the simulation finishes, since Lett teaches a feedback loop within the simulation process [p.11-12, 22, and 36], which suggests the use of data after simulation finishes, and since one skilled in the art would have recognized methods for passing data back into a system after simulation with predictable results, as shown by Cook, for the benefit of obtaining data consistency and improving overall efficiency [Cook, Section 3.3, p.10].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have modified the computational method and system of Lett by restoring the simulation context, with a reasonable expectation of success, since Lett shows storing simulation programs and related parameters to memory, as set forth above, and since one skilled in the art would have recognized that any simulation programs and parameters that have been stored in memory can be READ again (i.e. restored) with predictable results, as shown by Cook. The motivation would have been to combine prior art elements according to known methods to yield predictable results

Claims 4, 15, 24, 31, and 37-50 are rejected under 35 U.S.C. 103(a) as being made obvious by Lett et al. (WO 02/099736; Published 12 December, 2002; IDS filed 11/08/2004), in view of Cook (The Design of a Simulation System for Persistent Object

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Storage Management; University of Colorado; March 1993; p.1-23), as applied to claims 1-3, 5-14, 16-23, 25-30, 32-36, above, and further in view of Fox et al. (WO 03/042857, Published 22 May 2003; IDS filed 11/08/2004), and in view of Potts et al. (US 6,882,940; Filed Aug. 10, 2001).

Lett and Cook make obvious a method, program, and system for simulating biological processes using a block diagram simulation model, as set forth above. Additionally, Lett teaches a display for displaying simulation results to a user [See at least Fig. 1 and 2], as in claim 46.

Lett and Cook do not teach modifying a model of a biological process wherein the process is a chemical reaction, as in claims 37-39, 41-45, and 48-50.

Lett and Cook do not teach generating an event signal when the difference between the result and data gathered from the device exceeds a threshold, as in claims 4, 15, 24, 31, 40, and 47.

Fox teaches a method and system for inferring biochemical interaction networks including chemical reactions from dynamical or static experimental data, and a database of possible interactions [0065]. The simulation process operates according to a block diagram and includes the use of threshold values [Fig. 7, Fig. 8].

Potts teaches a prediction system with a modeling environment that allows for user-settable threshold levels [Col. 13, lines 20-25] and functionality for generating an alert signal when a measured signal is outside of the predetermined range of values [Co. 7, lines 20-23].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have alternatively modeled a chemical reaction, as taught by Fox, using the method, program, and system made obvious by Lett and Cook, with a reasonable expectation of success, since Lett suggests biological modeling software that models chemical reactions using experimental microscopic image data with predictable results [p.5, and p.7-9], and since Fox specifically employs a block diagram for simulating chemical reactions from experimental data [0065, Fig. 7, Fig. 8]. The motivation would have been to predict new interactions for the biological system being studied, as suggested by Fox [Abstract].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have generated an event signal when the difference between the result and data gathered from the device exceeds a threshold, using the method, program, and system made obvious by Lett and Cook, with a reasonable expectation of success, since Fox suggests the use of thresholds in a block diagram simulation process with predictable results, as set forth above, and since Potts employs software programming for generating an alert signals when signals are outside of threshold ranges with predictable results [Co. 7, lines 20-23]. The motivation would have been to improve simulation by generating warning messages when there are images with statistical differences between them, as suggested by Lett [p.15].

Response to Arguments

Applicant's arguments, filed 02/18/2011, have been fully considered but are not persuasive for the following reasons. It is noted that the Beckerle reference is withdrawn

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in view of applicant's amendments (which deleted the term "persistently"). Therefore arguments directed to Beckerle are moot.

In response to applicant's argument(s) on page(s) 15 that the combination of Lett and Cook do not teach storing a simulation context by registering an area of memory that constitutes the simulation context, the examiner has reviewed the specification and cannot find anything functionally or structurally unique about the claimed simulation context, and cannot find any limiting definition or an illuminating discussion for a "simulation context" that serves to distinguish it from being interpreted as a simulation program comprising different variables, as taught by Lett. Therefore Lett teaches a simulation context as claimed. While Lett does not teach storing a simulation context by registering an area of memory that constitutes the simulation context, as in claims 1, 12, 22, and 28, this limitation would have been obvious for the reasons discussed above.

In response to applicant's argument(s) on page(s) 16 that Cook does not teach "storing/restoring" a simulation context, a review of the specification does not provide any limiting definition or illuminating discuss for the term "restoring" such that is reads on anything other than simply re-reading a file stored in a database, which would have been obvious since one skilled in the art would have recognized that any simulation programs and parameters that have been stored in memory can be READ again (i.e. restored) with predictable results, as discussed above.

In response to applicant's argument(s) on page(s) 16 that Lett and Cook fail to teach registering an area of memory that constitutes a simulation context, this limitation, as best understood, simply reads on storing a simulation program to an area of

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memory, which would have been obvious since one skilled in the art would have recognized that methods for writing programs and related data to memory, such as physical hardware memory, requires registering it to specific locations (i.e. area) within the physical memory, as discussed above.

In response to applicant's argument(s) on page(s) 16-19 that Fox and Potts do not cure the deficiencies of Lett and Cook, as described above, Fox and Potts were not relied upon as teachings for these limitations. Therefore applicant's arguments are not persuasive for the reasons set forth above.

For the above reasons, the examiner maintains that the combination of references teaches and/or makes obvious all aspects of the claimed limitations. Accordingly, this rejection is MAINTAINED.

Double Patenting Rejection

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

The conclusion of obviousness-type double patenting is made in light of these factual determinations. Any obviousness-type double patenting rejection should make

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clear: (A) The differences between the inventions defined by the conflicting claims; and (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is anticipated by, or would have been an obvious variation of , the invention defined in a claim in the patent.

Claims 1, 12, 22, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 3 of copending Application No. 10/783552 in view of Lett and Cook.

The differences between the inventions defined by the conflicting claims are as follows: the copending claims are drawn to simulations that are a species of the instant claims, wherein the species “chemical reactions” are a species of biological process. Furthermore, the copending claims do not recite storing a simulation context by registering an area of memory that constitutes the simulation context, and making the simulation context available after the simulation finishes. However, a person of ordinary skill in the art would conclude that the invention defined in the instant claims at issue would have been an obvious variation of the claims of the cited copending application in view of the teachings of Lett and Cook, since one skilled in the art would have recognized that writing programs and related data to memory, such as physical hardware memory, requires registering it to specific locations (i.e. area) within the physical memory, as shown by Lett and Cook, and since one skilled in the art would have recognized methods for passing data back into a system after simulation with predictable results, as shown by Cook, for the benefit of obtaining data consistency and improving overall efficiency [Cook, Section 3.3, p.10].

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's statement, filed 02/18/2011, that a terminal disclaimer will be filed if needed is acknowledged but is not persuasive as no such disclaimer has yet been filed. Accordingly, this rejection is MAINTAINED.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 11am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

Art Unit 1631

/PW/

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631